

## REMARKS

After entry of this paper, claims 1-16 and 25-28 are pending. Claims 1 and 28 are amended to correct minor clerical errors. No new matter is added by these amendments.

### **35 USC § 112, Second Paragraph Rejection**

*Claims 1-16 and 25-28 are rejected under 35 USC § 112, second paragraph.*

*The Examiner asserted that a definition for (ii) was not provided in claims 1 and 28.*

Applicants respectfully request reconsideration and withdrawal of this rejection for the following reason.

In an effort to place the application in condition for allowance, Applicants have amended claims 1 and 28 by correcting a clerical error. Specifically, Applicants deleted reference to the R<sup>5</sup> “b)” option and inserted in place thereof “(ii)”.

Reconsideration of this rejection is requested.

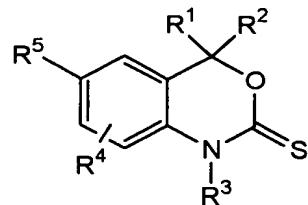
### **35 USC § 103(a) Rejection**

*Claims 1-16 and 25-28 are rejected under 35 USC § 103(a) over International Patent Publication No. WO 00/66570 ('570) and Applicants' acknowledgement on page 4, lines 3-5 of Applicants' specification in view of US Patent Application Publication No. 2002/0061875 (Gast).*

*The Examiner asserted that one would have been motivated to employ the cyclothiocarbamate derivatives of '570 for the progestins of Gast because each function as progesterone agonists.*

Applicants respectfully request reconsideration and withdrawal of this rejection because the combination of '570 and Gast does not suggest the present invention.

On page 4 of the present specification, Applicants simply refer to the compounds of '570, which are progesterone receptor (PR) agonists (progestins) of the following structure:



‘570 makes a general statement that “PR agonists...are used in birth control formulations, typically in the presence of an ER agonist, alternatively they may be used in conjunction with a PR antagonist”. ‘570 does teach or suggest any specific progestins that can be utilized for contraception *when combined with a selective estrogen receptor modulator*. Gast fails to provide this suggestion.

Gast is drawn to methods of providing contraception by administering a combination of non-uterotrophic anti-estrogens and progestins. Gast only refers to a limited number of specific progestins that can be utilized. Gast does not teach or suggest that progestins other than those specifically noted can be utilized. Nor does Gast teach or suggest that the specific progestins of the present invention can be used in combination with anti-estrogens. Therefore, the combination of Gast with ‘570 does not teach or suggest the present invention.

In making an obviousness rejection, the Examiner is required to consider the size of the genus claimed (MPEP 2144.08). Therefore, in the present rejection, the Examiner is required to consider the size of the genus of progestins, of which one of skill in the art would readily recognize as being considerably large. Such motivation to select the claimed species or subgenus must be taught by the prior art.<sup>1</sup> This motivation is required in order for a proper obviousness rejection to be made. This motivation is only provided by the Applicants’ disclosure.

Gast alone or in combination with ‘570 does not provide the required motivation to select the progestins of ‘570 and combine the same with any of the anti-estrogens of Gast.

Therefore, no combination of Gast with ‘570 and Applicants’ acknowledgement on page 4 of the specification teaches or suggests the present invention.

Reconsideration of this rejection is requested.

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<sup>1</sup> *In re Deuel*, 51 F. 3d at 1558-59; 34 USPQ2d at 1215.

### **Double Patenting Rejection**

*Claims 1-16 and 25-27 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 91 and 92 and the claims on which they directly or indirectly depend of US Patent No. 6,436,929 ('929) or claims 57, 83, and 97 and the claims on which they directly or indirectly of US Patent No. 6,509,334 ('334) in view of '570 cited above and Gast cited above.*

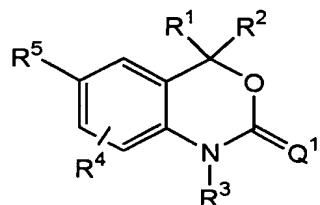
Applicants respectfully request reconsideration and withdrawal of this rejection for the following reason.

Upon reviewing the outstanding Office Action, Applicants note that the Examiner did not provide an explanation of how the combination of the cited claims of '929' or '334' with '570' and Gast assertedly makes obvious the present invention. The Examiner did not properly combine '570' or Gast with the claims of '929' or '334' for what is required to set forth a proper double patenting rejection.

However, in an effort to place the application in condition for allowance and to properly respond to the outstanding rejection, Applicants have provided the following comments regarding the improper combination of the cited claims of '929' or '334' with '570' and Gast. '570' and Gast are discussed in detail above.

#### None of '570, Gast, '929 (Claims 90 and 91), or 334 (Claims 56 and 83) Teach or Suggest the Present Invention

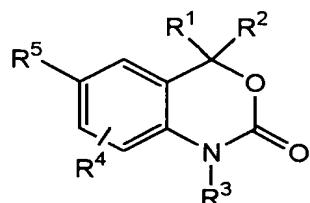
Claim 91 of '929' is drawn to a method of inducing contraception in a mammal by administering a compound of the following formula. Similarly, claim 90 of '929' is drawn to a pharmaceutical composition including this compound. The compounds of claims 90 and 91 are progestins.



$Q^1 = NR^7$  or  $CR^8R^9$ , but not S.

Since '929 and '570 have identical specifications ('570 claims priority of '929), the compounds claimed in '929 are identical to the compounds discussed in '570. Neither '929 nor '570 teach or suggest the present invention.

Claim 56 of '334 is drawn to a compound of the following structure, where R<sup>5</sup> is a thiophene group. Claim 83 is also drawn to this compound, where R<sup>5</sup> is a 3-bromo-4-fluoro-phenyl group. Since '334 does not contain a claim 97, as suggested by the Examiner, the following arguments do not include any reference to this claim. The compounds of claims 56 and 83 are effective as anti-progestins.



The claimed compound of '334 requires that an oxygen heteroatom be bonded to the backbone of the molecule in position-2 through a double bond. Claims 56 and 83 do not permit a S, NR<sup>6</sup>, or CR<sup>8</sup>R<sup>9</sup> group to be bound to the backbone of the molecule at position-2 through a double bond. Therefore, the compounds claimed in '334 differ structurally than the claimed compounds of Applicants' present invention and do not teach or suggest the present invention.

No Combination of '929 (Claims 90 and 91) or '334 (Claims 56 and 83) With '570 and Gast Teaches or Suggests the Present Invention

For the reasons provided above, given the genus of progestins known in the art, one would not be motivated to substitute the specific progestins of '929 or '570 for the progestins of Gast for administration with the anti-estrogens recited therein with the expectation that the same would be successful in contraception.

Further, given the differences in biological activities between progestins and anti-progestins, one would not expect that progestins could be substituted with anti-progestins in any formulation. One would therefore not expect that the progestins of Gast could be substituted with the anti-progestins of '334 for use in contraception.

For these reasons, one would not be motivated to combine the progestins of '929 or '570 or the anti-progestins of '334 with the anti-estrogens of Gast with the expectation that the same would be useful in contraception.

If the Examiner does not accept these arguments and thereby withdraw the outstanding double patenting rejection, Applicants respectfully request that the Examiner provide an explanation for the combination of the cited claims of '292 or '334 with '570 and Gast and provide Applicants with a second opportunity to properly address the combination of the claims of '929 or '334 with '570 and Gast.

Reconsideration of this rejection is requested.

### **Hodgen Document**

*The Examiner asserted that US Patent No. 6,258,802 (Hodgen) shows the state of the art.*

Applicants agree that Hodgen does not teach or suggest Applicants' invention.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees to our Deposit Account Number 08-3040.

Respectfully submitted,

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